UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/282,471	03/31/1999	INDU PARIKH	401865/SKYEPHARMA	8677

35437 7590 10/02/2006

MINTZ LEVIN COHN FERRIS GLOVSKY & POPEO
666 THIRD AVENUE
NEW YORK, NY 10017

EXAMINER	
KISHORE, GOLLAMUDI S	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 10/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/282,471	PARIKH, INDU	
	Examiner	Art Unit	
	Gollamudi S. Kishore, Ph.D	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *34-36,38-48,50,52 and 55-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34-36, 38-48, 50, 52, and 55-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment dated 7-5-06 is acknowledged.

Claims included in the prosecution are 34-36, 38-48, 50, 52, and 55-67.

In view of the amendments to the claims, the 112, second paragraph rejection is withdrawn.

In view of the terminal disclaimers, the double patenting rejections of claims over the claims in the copending applications 10/260,788 and 09/443,862 are withdrawn.

The double patenting rejections over the claims in 10/443,772 and 09/443,863 however, are maintained.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 34-36, 38-48, 50, 52 and 55-67 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 45-97 of copending Application No. 10/443,772. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims in both applications are drawn to the same method of preparing the microparticles of fenofibrate. The method claims in the copending application recite in addition the step of adding the bulking/releasing agents in order to prepare rapidly disintegrating solid dosage forms of fenofibrate. It would have been obvious to one of ordinary skill in the art to utilize additional steps in instant process to prepare appropriate dosage forms of fenofibrate such as rapidly disintegrating forms claimed in the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that the claims of the 772 application are not directed to a method of making fenofibrate microparticles, but rather directed to a process of preparing a rapidly disintegrating solid dosage form comprising stabilized fenofibrate particles and that the process claimed in the 772 application requires components and steps that function as particularly described in the claims to produce the rapidly disintegrating solid dosage form. These arguments are not persuasive since the initial

process conditions recited in the claims of copending application results in the same particles of fenofibrate as in instant claims. The claims in said copending application thus, encompasses instant method steps. Instant claims do not exclude the additional process steps recited in the claims of said copending application. The rejection is maintained.

3. Claims 34-36, 38-48, 50, 52 and 55-67 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 50-52, 54-92 and 97-131of copending Application No. 09/443,863. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims in both applications are drawn to the same method of preparing the microparticles. The method claims in the copending application recite in addition the step of adding the bulking/releasing agents in order to prepare rapidly disintegrating solid dosage forms and the independent claims in addition recite 'water insoluble or poorly water soluble drug'. However, the dependent claims (129-131 for example) specify that the drug is fenofibrate. It would have been obvious to one of ordinary skill in the art to utilize additional steps in instant process to prepare appropriate dosage forms of fenofibrate such as rapidly disintegrating forms claimed in the copending application. Instant species of the drug, 'fenofibrate' is anticipated by the generic 'water insoluble drug' in the claims of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant once again argues that the claims of the 863 application are not directed to a method of making fenofibrate microparticles, but rather directed to a process of preparing a rapidly disintegrating solid dosage form comprising stabilized fenofibrate particles and that the process claimed in the 772 application requires components and steps that function as particularly described in the claims to produce the rapidly disintegrating solid dosage form. These arguments are not persuasive since the initial process conditions recited in the claims of copending application results in the same particles of fenofibrate as in instant claims. The claims in said copending application thus, encompasses instant method steps. Instant claims do not exclude the additional process steps recited in the claims of said copending application. The rejection is maintained.

4. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Woodward Michael can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ S Kishore

Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK